510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K261632

B Applicant

Cepheid

C Proprietary and Established Names

Xpert Hemorrhagic Fever

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QVR	Class II	21 CFR 866.4000 - Device To Detect And Identify Biothreat Microbial Agents In Human Clinical Specimens	MI - Microbiology
OOI	Class II	21 CFR 862.2570 - Instrumentation for clinical multiplex test systems	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

A Dual 510(k)/Waiver submission to obtain a substantial equivalence determination for the Cepheid Xpert Hemorrhagic Fever test.

B Measurand:

The assay detects and identifies nucleic acids of the following organisms: Ebola virus, Crimean-Congo hemorrhagic fever (CCHF) virus, Marburg virus, and Lassa virus.

C Type of Test:

Multiplex Nucleic Acid Amplification Test

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Xpert Hemorrhagic Fever test, performed on the GeneXpert Edge X system, is an automated multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative in vitro detection and identification of RNA from multiple biothreat agents:

• Ebola virus (including Zaire, Sudan, Taï Forest, and Bundibugyo, not differentiated)

• Crimean-Congo hemorrhagic fever (CCHF) virus

• Marburg virus

• Lassa virus

The Xpert Hemorrhagic Fever test uses EDTA-treated whole blood specimens collected by capillary or venous draw from individuals with signs and symptoms of the suspected infections and/or individuals who are at risk for exposure or may have been exposed to these agents.

The Xpert Hemorrhagic Fever test is indicated as an aid in the diagnosis of viral hemorrhagic fevers and results should be used in conjunction with other clinical, epidemiologic and laboratory data in accordance with the guidelines provided by the Centers for Disease Control and Prevention (CDC) and United States Department of Defense (DoD).

The Xpert Hemorrhagic Fever test results are for the presumptive identification of Ebola, CCHF, Marburg and Lassa viruses. Definitive identification requires additional testing and confirmation procedures in consultation with the appropriate public health authorities for whom reports may be necessary. Positive results do not rule out co-infection with organisms not included in the Xpert Hemorrhagic Fever test. The organism(s) detected may not be the definite cause of symptoms. Negative results do not preclude infection with these agents and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

The Xpert Hemorrhagic Fever test is for use only by United States Department of Defense laboratories having appropriate personal protective equipment (PPE) and other safety precautions including personnel trained in the safe handling of diagnostic clinical specimens potentially containing highly infectious agents. Viral hemorrhagic fevers are nationally notifiable diseases caused by biothreat agents and reporting of these diseases should be coordinated with the appropriate Department of Defense and public health authorities.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

The Xpert HF test is performed on the GeneXpert Edge X system

IV Device/System Characteristics:

A Device Description:

The Xpert Hemorrhagic Fever (Xpert HF) test is an automated *in vitro* diagnostic test for the qualitative detection and identification of RNA from Ebola virus (strains Zaire, Sudan, Taï Forest, and Bundibugyo, not differentiated), CCHF virus, Marburg virus, and Lassa virus in EDTA-treated whole blood specimens collected by capillary or venous draw from individuals with signs and symptoms of the suspected infections and/or individuals who are at risk for exposure or may have been exposed to these agents.

The Xpert HF test includes reagents for the detection of RNA from Ebola virus (strains Zaire, Sudan, Taï Forest, and Bundibugyo, not differentiated), CCHF virus, Marburg virus, and Lassa virus in EDTA-treated capillary or venous whole blood specimens. A Sample Processing Control (SPC), a Sample Adequacy Control (SAC), and a Probe Check Control (PCC) are also included in the cartridge. The SPC is present to control adequate extraction and processing of the target sequences and to monitor for the presence of inhibitors in the PCR reaction. The SAC ensures that sufficient human cells have been added in test cartridge. The PCC verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

Venous and capillary whole blood specimens collected into EDTA anticoagulant tubes are added to an off-board sample reagent (SR) vial in which the sample is inactivated. The inactivated sample is then added to the Xpert HF cartridge before being loaded onto the GeneXpert Edge X instrument, automated sample processing, and real-time RT-PCR for the detection of these viral RNAs.

The Xpert HF test is designed for use with fingerstick K_2-EDTA whole blood (CWB) or EDTA-treated whole blood obtained from venous draw (VWB). The ancillary EDTA anticoagulant whole blood collection tubes verified and/or validated for use with the Xpert HF test included:

- BD Microtainer Contact-Activated Lancet (P/N 366594 or P/N 366578) (K223243)
- BD Microtainer Blood Collection Tubes (P/N 3665974) for capillary whole blood collection
- BD Vacutainer Blood Collection Tubes for venous whole blood collection (K231373)
    - P/N 367841 (2 mL)
    - P/N 366643 (10 mL)
    - P/N 367899 (6 mL)

These ancillary collection tubes allow VWB and CWB specimens from patients to be collected, preserved and transported to the laboratory prior to analysis with the Xpert HF test.

The results are interpreted from measurement of fluorescent signals by the Cepheid OS X software and are shown in the “Result Summary Page”. The Xpert HF test provides test results for Ebola, CCHF, Marburg and Lassa. If an error is encountered, “NO RESULT-REPEAT

TEST" and "INSTRUMENT ERROR" test results are also reported and the user is instructed to repeat the test. Test results are obtained in approximately 60 minutes.

B Principle of Operation:

The Xpert HF test uses reverse transcriptase to transcribe viral RNA from Ebola, Lassa, CCHF and Marburg virus into cDNA and real-time PCR for gene-specific sequence amplification. Amplified DNA is detected by fluorogenic target-specific probe hybridization followed by 5'-nuclease cleavage of the probe to release the fluorophore (TaqMan). The Xpert HF test uses lyophilized reagents in the form of freeze-dried beads, which provide enzymes, dNTPs, primers, probes and buffers to support PCR when reconstituted.

C The GeneXpert Edge X system:

The Xpert HF test is performed on the GeneXpert Edge X system, which consists of the instrument and a mobile tablet with preloaded software for performing the test and viewing the results, and an optional power unit as shown in Figure 1.

Figure 1. GeneXpert Edge X System

The GeneXpert Edge X system was reviewed previously in submission K253653.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Xpert Hemorrhagic Fever

B Predicate 510(k) Number(s):

K253653

C Comparison with Predicate(s):

Device & Predicate	K261632	K253653

Device(s):		
Device Trade Name	Xpert Hemorrhagic Fever	Xpert Hemorrhagic Fever
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Xpert Hemorrhagic Fever test, performed on the GeneXpert Edge X system, is an automated multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative *in vitro* detection and identification of RNA from multiple biothreat agents: • Ebola virus (including Zaire, Sudan, Taï Forest, and Bundibugyo, not differentiated) • Crimean-Congo hemorrhagic fever (CCHF) virus • Marburg virus • Lassa virus The Xpert Hemorrhagic Fever test uses EDTA-treated whole blood specimens collected by capillary or venous draw from individuals with signs and symptoms of the suspected infections and/or individuals who are at risk for exposure or may have been exposed to these	The Xpert Hemorrhagic Fever test, performed on the GeneXpert Edge X system, is an automated multiplex real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative *in vitro* detection and identification of RNA from multiple biothreat agents: • Ebola virus (including Zaire, Sudan, Taï Forest, and Bundibugyo, not differentiated) • Crimean-Congo hemorrhagic fever (CCHF) virus • Marburg virus • Lassa virus The Xpert Hemorrhagic Fever test uses EDTA-treated whole blood specimens collected by capillary or venous draw from individuals with signs and symptoms of the suspected infections and/or individuals who are at risk for exposure or may have been exposed to these

	agents. The Xpert Hemorrhagic Fever test is indicated as an aid in the diagnosis of viral hemorrhagic fevers and results should be used in conjunction with other clinical, epidemiologic and laboratory data in accordance with the guidelines provided by the Centers for Disease Control and Prevention (CDC) and United States Department of Defense (DoD). The Xpert Hemorrhagic Fever test results are for the presumptive identification of Ebola, CCHF, Marburg and Lassa viruses. Definitive identification requires additional testing and confirmation procedures in consultation with the appropriate public health authorities for whom reports may be necessary. Positive results do not rule out co-infection with organisms not included in the Xpert Hemorrhagic Fever test. The organism(s) detected may not be the definite cause of symptoms. Negative results do not preclude	agents. The Xpert Hemorrhagic Fever test is indicated as an aid in the diagnosis of viral hemorrhagic fevers and results should be used in conjunction with other clinical, epidemiologic and laboratory data in accordance with the guidelines provided by the Centers for Disease Control and Prevention (CDC) and United States Department of Defense (DoD). The Xpert Hemorrhagic Fever test results are for the presumptive identification of Ebola, CCHF, Marburg and Lassa viruses. Definitive identification requires additional testing and confirmation procedures in consultation with the appropriate public health authorities for whom reports may be necessary. Positive results do not rule out co-infection with organisms not included in the Xpert Hemorrhagic Fever test. The organism(s) detected may not be the definite cause of symptoms. Negative results do not preclude

	infection with these agents and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. The Xpert Hemorrhagic Fever test is for use only by United States Department of Defense laboratories having appropriate personal protective equipment (PPE) and other safety precautions including personnel trained in the safe handling of diagnostic clinical specimens potentially containing highly infectious agents. Viral hemorrhagic fevers are nationally notifiable diseases caused by biothreat agents and reporting of these diseases should be coordinated with the appropriate Department of Defense and public health authorities.	infection with these agents and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. The Xpert Hemorrhagic Fever test is for use only by United States Department of Defense laboratories having appropriate personal protective equipment (PPE) and other safety precautions including personnel trained in the safe handling of diagnostic clinical specimens potentially containing highly infectious agents. Viral hemorrhagic fevers are nationally notifiable diseases caused by biothreat agents and reporting of these diseases should be coordinated with the appropriate Department of Defense and public health authorities.
Specimen Type	Venous Whole Blood and Capillary Whole Blood collected in EDTA tube	Same
Technological Principles	Automated Nucleic Acid Extraction, Detection and Results Interpretation	Same
Single Use	Yes	Same
Assay Results	Qualitative	Same
Test Interpretation	Automated test interpretation and report generation. User cannot access raw data	Same

Time to Result	About 1 hour	Same
Analytes Detected	Nucleic acids from: • Ebola virus (including Zaire, Sudan, Taï Forest, and Bundibugyo, not differentiated) • Crimean-Congo hemorrhagic fever (CCHF) virus • Marburg virus • Lassa virus	Same
Internal Control	Sample Processing Control (SPC) Sample Adequacy Control (SAC) Probe Check Control (PCC)	Same
Instrument System	Cepheid GeneXpert Edge X system	Same
Software	Cepheid OS X 1.1 or higher	Same
General Device Characteristic Differences		
Testing Environment	CLIA Waived testing environments	CLIA Moderate Complexity testing environments

VI Standards/Guidance Documents Referenced:

- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- CLSI EP07-A3 Interference Testing in Clinical Chemistry; Approved Guideline – 3rd Edition
- CLSI EP37 Supplemental Tables for Interference Testing in Clinical Chemistry - 1st Edition
- CLSI EP12 Evaluation of Qualitative Binary Output Examination Performance – 3rd Edition
- CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – 2nd Edition
- CLSI EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline – 2nd Edition
- IEC 61326-1:2020 Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements – 3rd Edition
- IEC 61326-2-6:2020 Electrical equipment for measurement control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment – 3rd Edition
- IEC 62304:2015 Medical device software - Software life cycle processes – Edition 1.1

- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests – Edition 4.1

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Reproducibility of the Xpert HF test at waived study sites was established previously. The device is unchanged from the predicate and additional studies were not required. Please refer to the public decision summary for K253653.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Interference from endogenous and exogenous sources was evaluated previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K253653.

4. Detection Limit and Assay Reportable Range:

   The detection limits for analytes detected by the Xpert HF test were established previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K253653.

   Assay reportable range is not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   External controls and stability claims remain unchanged as described in the public decision summary for K253653. The device is unchanged from the predicate and additional studies were not required.

6. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

This is a dual 510(k)/CLIA waiver submission. A user comparison study was conducted to evaluate whether the Xpert HF test has comparable performance in the hands of untrained operators in CLIA-waived settings. Please see CW260013 for the study protocol and results.

2. Matrix Comparison:

Equivalent performance of the Xpert HF test between K_2-EDTA vs. K_3-EDTA venous whole blood was established previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K253653.

C Clinical Studies:

1. Xpert Hemorrhagic Fever test performance with trained users:

The Xpert HF test was previously cleared (K253653) based on results from a prospective, multi-center, blinded clinical study. The objective of the clinical study was to evaluate the clinical performance of the Xpert HF test on the GeneXpert Edge X system by trained users in a laboratory setting. Study subjects were asymptomatic or symptomatic for fever and paired EDTA-treated venous whole blood and capillary whole blood were collected. As there were no documented outbreaks of viral hemorrhagic fever (VHF) in the U.S. at the time of the study, all specimens collected were assumed to be negative for VHF targets. Positive samples were contrived with live VHF cultures and non-contrived specimens served as negative samples. No comparator method was utilized since the positive percent agreement (PPA) and negative percent agreement (NPA) of the Xpert HF test were determined relative to the expected results of contrived samples and non-contrived specimens, respectively. To demonstrate that the Xpert HF test results from this study remained unchanged with the latest COS X 1.1 software version intended for the test, the original clinical study data generated on the GeneXpert Edge X system running COS X 1.0 were reanalyzed with COS X 1.1.

2. Xpert Hemorrhagic Fever test performance with untrained users:

To support the use of the Xpert HF test by untrained users in a CLIA-waived environment, a second study was conducted in which the performance of the Xpert HF test was compared between trained users in a laboratory setting and untrained users at three sites representative of a CLIA-Waived test settings. Paired EDTA-treated VWB and EDTA-treated CWB specimens were collected at a single US site from healthy donors. Positive samples were created by adding VWB and CWB to Sample Reagent containing pseudoviral constructs carrying viral RNA for one of the four Xpert HF analytes (Ebola virus, Marburg virus, Crimean-Congo Hemorrhagic Fever [CCHF] virus, and Lassa virus). The SR vials contrived with pseudoviral constructs were contrived to a final concentration of either 1-2X Limit of Detection (LoD) or 3X LoD. It was assumed that all specimens collected at the U.S. site were negative for VHF targets since there were no documented outbreaks of VHF in the U.S. during the study period. Clinical CWB or VWB samples in SR which did not contain pseudoviral constructs were considered negative and evaluated for NPA. The study was conducted between October 2024 and March 2025.

Trained or untrained users added the VWB or CWB specimens to SR as part of the sample preparation and subsequently tested the individually prepared contrived positive or negative specimens on the Xpert HF test. Performance of the Xpert HF test was assessed

relative to the expected positive and negative results of the contrived samples and non-contrived specimens.

a. *Operators*

Nine untrained operators (3 per CLIA-waived site) and three trained operators (all at one laboratory site) participated in the study. All untrained operators were non-laboratory healthcare personnel with no prior experience in CLIA moderate/high complexity laboratory testing, no prior training on the Xpert HF test, and diverse educational and work experience backgrounds. Information on the operators' current job title, education level, and any laboratory or relevant work experience was provided to support untrained operators were representative of untrained, naïve operators in the CLIA-waived setting. Trained operators met the qualifications to perform CLIA moderate to high complexity testing. Xpert HF performance in the hands of untrained operators was compared to performance of the trained operators.

b. *Instructions for Use*

Trained users performed testing according to the Instructions for Use (IFU) but were also provided with the Quick Reference Instructions (QRI). Untrained users performed testing according to the QRI but also had access to the IFU. Untrained users were self-trained on the Xpert HF test and the GeneXpert Edge X system but were not provided with any additional training on the test or system.

c. *Subjects*

A total of 725 subjects were enrolled in the study. Each subject provided either paired CWB and VWB specimens or CWB specimens only. From the VWB specimens, four samples were prepared and from CWB specimens two samples were prepared. A total of 2910 negative and contrived positive samples (1460 VWB and 1450 CWB) were prepared. Six samples (4 VWB, 2 CWB) were excluded due to ineligibility and an additional four samples were excluded due to protocol deviations resulting in 2900 samples included in the Xpert HF testing.

Inclusion Criteria:

- Documentation that the study participant provided informed consent/assent as required by the reviewing IRB. Documented receipt of Experimental Bill of Rights all participants enrolled in applicable states. In addition, minors must have provided assent or informed consent of parent(s) or legal guardian(s).
- Minors were defined as less than 18 years of age, unless otherwise defined by state or country requirements.
- Participant was 14 years of age or older.
- Participant was "healthy" per the study protocol definition.
- Participant was able and agreed to provide the following specimen(s) for study purposes, CWB specimens (≥500 µL total volume) and VWB specimen (≥1 mL total volume), or CWB specimens (≥500 µL total volume)

Exclusion Criteria:

- Healthcare professional did not feel the participant was a suitable candidate for VWB and CWB collection.
- Participant was vaccinated with a Hemorrhagic Fever live virus vaccine within the past 28 days.
- Participant was previously enrolled into this protocol.
- VWB and CWB specimens were not collected according to the manufacturer's instructions.

Subject demographic information for the prospective specimens available for performance assessments is presented in **Table 5**.

Table 5. Demographic Information for Study Subjects

Study Participants (N = 724)	
Gender	
Female	474 (65.5%)
Male	250 (34.5%)
Age Group (Years)	
14-21	82 (11.3%)
22-59	538 (74.3%)
≥60	104 (14.4%)
Race	
Asian	9 (1.2%)
Black/African American	179 (24.7%)
White	535 (73.9%)
Subject Declined to Answer	1 (0.1%)
Ethnicity	
Hispanic or Latino	5 (0.7%)
Not Hispanic or Latino	718 (99.2%)
Subject Declined to Answer	1 (0.1%)

d. *Performance Analyses*

The Xpert HF test on the GeneXpert Edge X system was evaluated relative to the expected results for the negative and contrived positive samples. This analysis was done for each analyte in both specimen types. Positive Percent Agreement was calculated as 100% x (TP / (TP + FN)). True positive (TP) indicates that the Xpert HF test had a positive result with positive contrived samples, and false negative (FN) indicates that the Xpert HF test had a negative result with positive contrived samples. Negative Percent Agreement (NPA) was calculated as 100% x (TN / (TN+ FP)). True negative (TN) indicates that the Xpert HF test result was negative for negative samples, and false positive (FP) indicates that the Xpert HF test result was positive for negative samples.

e. *Results*

The Xpert HF test performance relative to the expected results for the detection of the Crimean-Congo Hemorrhagic Fever analyte in CWB and VWB specimen types by trained and untrained users, including the PPA and NPA are presented in **Table 6**.

Table 6. Performance of Xpert HF for CCHF in CWB and VWB with Trained and Untrained Users

		Expected Results											
		Trained User						Untrained User					
		CWB			VWB			CWB			VWB		
		Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total
Xpert HF test	Pos.	91	0	91	91	0	91	91	0	91	91	0	91
	Neg.	0	360	360	0	360	360	0	360	360	0	364	364
PPA (95% CI)		100% (95.9-100.0%)			100% (95.9-100.0%)			100% (95.9-100.0%)			100% (95.9-100.0%)		
NPA (95% CI)		100% (98.9-100.0%)			100% (98.9-100.0%)			100% (98.9-100.0%)			100% (98.9-100.0%)		

Abbreviations: CI = Confidence Interval, Neg. = Negative, Pos. = Positive

The Xpert HF test performance relative to the expected results for the detection of the Ebola analyte in CWB and VWB specimen types by trained and untrained users, including the PPA and NPA are presented in **Table 7**.

Table 7. Performance of Xpert HF for Ebola in CWB and VWB with Trained and Untrained Users

		Expected Results											
		Trained User						Untrained User					
		CWB			VWB			CWB			VWB		
		Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total
Xpert HF test	Pos.	90	0	90	90	0	90	89	0	89	90	0	90
	Neg.	0	360	360	0	360	360	1[a]	360	361	0	364	364
PPA (95% CI)		100% (95.9-100.0%)			100% (95.9-100.0%)			98.9% (94.0-99.8%)			100% (95.9-100.0%)		
NPA (95% CI)		100% (98.9-100.0%)			100% (98.9-100.0%)			100% (98.9-100.0%)			100% (99.9-100.0%)		

Abbreviations: CI = Confidence Interval, Neg. = Negative, Pos. = Positive

[a.] Discrepant analysis identified clotting in the CWB sample as the probable root cause for the FN Xpert HF test result.

The Xpert HF test performance relative to the expected results for the detection of the Lassa analyte in CWB and VWB specimen types by trained and untrained users, including the PPA and NPA are presented in **Table 8**.

Table 8. Performance of Xpert HF for Lassa in CWB and VWB with Trained and Untrained Users

		Expected Results											
		Trained User						Untrained User					
		CWB			VWB			CWB			VWB		
		Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total
Xpert HF test	Pos.	90	0	90	91	0	91	90	0	90	91	0	91
	Neg.	1[a]	360	361	0	360	360	1[a]	360	361	0	364	364
PPA (95% CI)		98.9% (94.0-99.8%)			100% (95.9-100.0%)			98.9% (94.0-99.8%)			100% (95.9-100.0%)		
NPA (95% CI)		100% (98.9-100.0%)			100% (98.9-100.0%)			100% (98.9-100.0%)			100% (99.9-100.0%)		

Abbreviations: CI = Confidence Interval, Neg. = Negative, Pos. = Positive

[a.] Discrepant analysis identified clotting in the CWB sample as the probable root cause for the FN Xpert HF test result.

The Xpert HF test performance relative to the expected results for the detection of the Marburg analyte in CWB and VWB specimen types by trained and untrained users, including the PPA and NPA are presented in **Table 9**.

Table 9. Performance of Xpert HF for Marburg virus in CWB and VWB with Trained and Untrained Users

		Expected Results											
		Trained User						Untrained User					
		CWB			VWB			CWB			VWB		
		Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total	Pos.	Neg.	Total
Xpert HF test	Pos.	92	0	92	91	0	91	91	0	91	92	0	92
	Neg.	0	360	360	0	360	360	1[a]	360	361	0	364	364
PPA (95% CI)		100% (96.0-100.0%)			100% (95.9-100.0%)			98.9% (94.1-99.8%)			100% (96.0-100.0%)		
NPA (95% CI)		100% (98.9-100.0%)			100% (98.9-100.0%)			100% (98.9-100.0%)			100% (99.0-100.0%)		

Abbreviations: CI = Confidence Interval, Neg. = Negative, Pos. = Positive

[a.] Discrepant analysis identified clotting in the CWB sample as the probable root cause for the FN Xpert HF test result.

f. *Non-determinate (ND) rate*

Of the 1448 CWB samples tested with the Xpert HF test, 11 ND results (1.5%, 11/724) were obtained by trained users and 10 ND results (1.4%, 10/724) were obtained by untrained users. Upon retesting, all samples produced a valid result and a final ND rate of 0% (0/724) for CWB samples.

Of the 1452 VWB samples tested with the Xpert HF test, 13 ND results (1.8%, 13/723) were obtained by trained users and 6 ND results (0.8%, 6/729) were obtained by untrained users. Upon retesting, 12 of the 13 VWB samples tested by trained users produced valid results and a final ND rate of 0.1% (1/723). For ND results obtained by untrained users, all 6 samples produced valid results and a final ND rate of 0% (0/729).

3. Clinical Cut-Off

Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Expected Values/Reference Range:

None of the rare Xpert HF target analytes were detected during the prospective clinical study conducted previously. The device is unchanged from the predicate and additional studies were not required. Refer to the public decision summary for K253653.

E Other Supportive Instrument Performance Characteristics Data:

Software and cybersecurity documentation was reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.